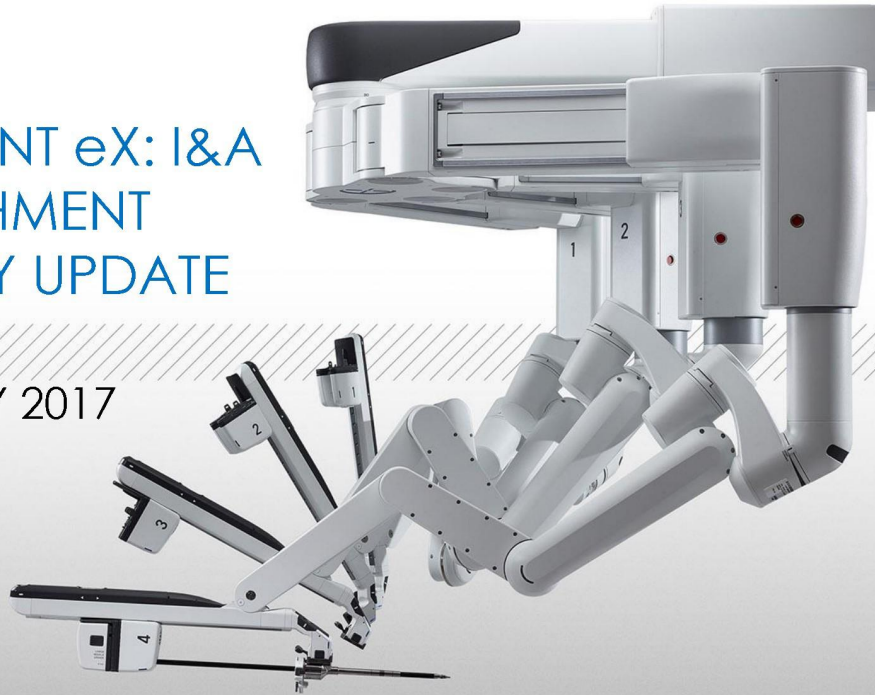


INTUITIVE
SURGICAL®

INSTRUMENT eX: I&A REFURBISHMENT FEASIBILITY UPDATE

30 JANUARY 2017



da Vinci Surgery

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Agenda

- Objective
- Executive Summary
- Assumptions
- Technical Assessment
- Manufacturing Assessment
- Logistics & Financial Assessment
- Market Assessment
- Recommendation & Metrics

Objective

- **Primary:** To drive increased procedure volume in cost sensitive regions by providing a lower priced instrument offering through reclamation and remanufacturing of ISI Core instruments
- **Secondary:** To reclaim expired instruments from the field to avoid the unauthorized reprogramming and/or remanufacturing which could impact product performance and patient safety



Executive Summary

- **Recommendation:** Instrument eX (exchange) Project to proceed with pilot at select hospitals in French and German markets with **green housing* instruments** to test assumption of market elasticity
- **Reclamation:** on a macro level should be decoupled from the Instrument eX pilot, and can commence at an estimated cost of \$12-22 per instrument
- **Legal/Regulatory:**

Redacted for Privilege

**Green Housing Instruments – manufactured as new with green cover and labeling which states “may contain remanufactured components”*

Assumptions

- dV procedure cost at specific hospitals (regions) is a market barrier to increased adoption
- Core Instruments are the priority target for remanufacture as there is less cost sensitivity on advanced procedures (Instruments)
- Program = Closed-Loop Refurbished Instrument program. 1-for-1 “like instrument” exchange of key refurbished instruments for selected hospitals
- Estimated price reduction for eX Instruments is 30% off current List Price for new
- Instruments will be remanufactured one time to original ISI specifications at 75% COGS of new

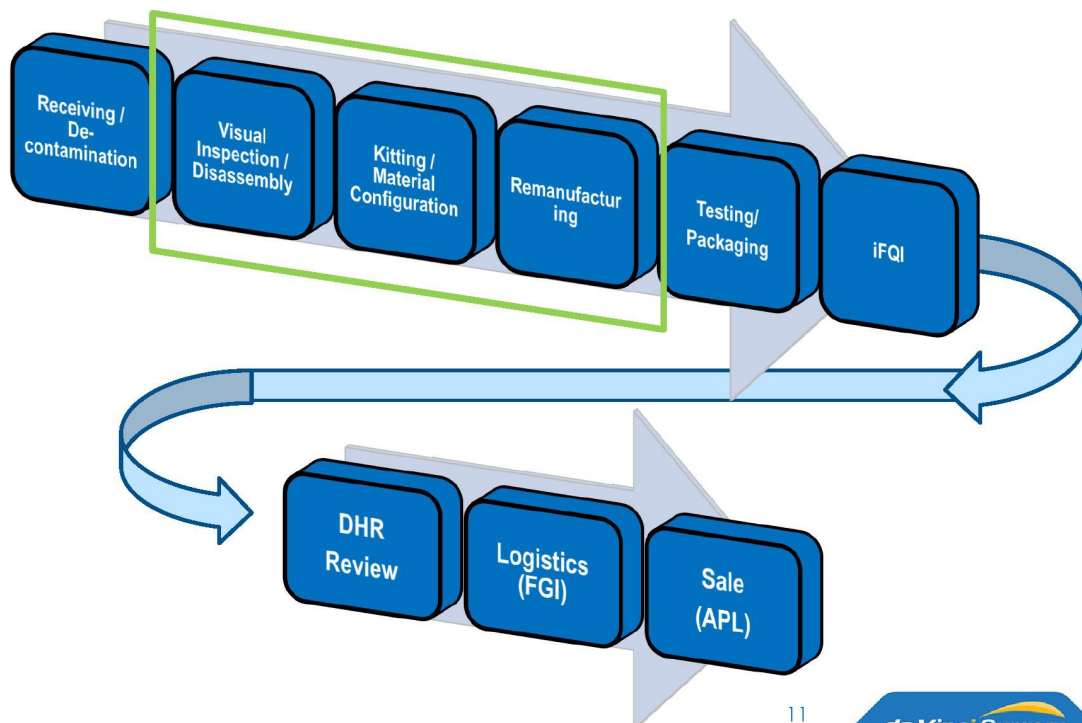


Technical Assessment

- *Summary:*
 - *Multiple engineering tests confirmed durability of components to be reused on FBF, LND, MCS and Prograsp*
 - *Confirmed minimum mandatory replacement parts*
 - *Recommendation to move forward with MCS, FBF, MBP, LND, and Prograsp*
 - *Full Design Verification & Reliability Testing to be done in parallel with Pilot*
 - *Baseline refurbishment times documented from rebuilds*



Manufacturing Assessment



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Manufacturing Assessment

- **Plant:** B950 (RMA) Sunnyvale
- **Facilities (Line Space):** 1000 sf
- **Facilities (Equipment):** 8mm (Xi) Line at \$1M
- **IT Support:** SAP/Agile updates ('rock')
- **Device History Record (DHR):**
 - Medium Complexity Option:
 - Part Numbering '-R' (i.e. 470006-05R)
 - Lot based recertification process (typically 20-100 units)
 - Product upgrades identified through work instruments



Options	Comments
1 Low Complexity	No component level traceability. Highest exposure during product recalls.
2 Medium Complexity	Lot based traceability. Requires modified IT processes. Evaluating whether level of traceability provided improves over option 1
3 High Complexity	Serialized instruments, highly burdensome, high level of traceability

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8mm (Xi) line could be reallocated to production use (but not interchangeable)

Low / Med / High – traceability vs costs (Risk vs Reward)

Work order has estimated processes costs of \$500 ea. Typically allocated over 50-150 instruments

Evaluating use of Lot# and Sequence# for tracking. Sequence# not visible across all business systems – provides some coverage

No intermixing or restocking of components, all virgin replacements (Parts are original or new)



Logistics – Costs

- **Reclaiming of Instruments by ISI:**
 - Costs (excludes return incentive(TBD)):
 - **Europe Reclamation for Disposal (Pilot): \$21.60/ea**
 - **US Reclamation for Refurb(Includes C&S): \$24.92/ea**
 - **US Reclamation for Disposal Only: \$12.17/ea**

- **Reclaiming of Instruments by 3rd Party:**
 - Costs: Evaluation currently in process

In-sourced:

Place collection containers at customer sites for “clean” expired instruments

Visit sites periodically to collect (via extension of SRS Team)

Bag, box, and return bins to processing/sorting site

Receive/log SKUs (by account)

Hand off SKUs that are to be refurbished to be cleaned

Dispose of material not reclaimed (e.g. ineligible SKUs, previously-refurbished SKUs & non-reclaimed parts)

Financial Analysis

- *Pilot Program*
 - *SV rmfg of US instr, France + Germany markets*
 - *Green Housing Pilot cost estimate ~\$100k - \$500k*
 - *Full implementation setup of \$2.5M for remanufacture of reclaimed Instruments*
 - *Product margin of 83% with green housing (6 point decrease compared to new builds)*

Xi MCS Example	List	DM	DL	OCOGS	CM \$	CM%
New	3,200	237	14	107	2,841	89%
25% DM Yield, SV	2,240	178	74	154	1,834	82%
47% DM Yield, SV	2,240	126	74	151	1,889	84%
Green Housing	2,240	237	14	129	1,860	83%
25% DM Yield, MX	2,240	178	7	154	1,901	85%
47% DM Yield, MX	2,240	126	7	151	1,956	87%



Customer Visits – France (hospitals)

Met with French Hospital Directors, Surgeons and Purchasing Managers to discuss the feasibility of adopting remanufactured *EndoWrist* Instruments and adherence to returning all expired instruments



- 2016 Procedures -- 283
- One da Vinci Xi Surgical System
- Two surgeon interviews (Thoracic and Urologist)
- Both confirmed they would perform more *da Vinci* procedures if costs per procedure would decrease
- Feasibility confirmed



- 2016 Procedures – 179
- One da Vinci Si Surgical System
- CEO and OR Director
- Surgeons charged 250€ per dV procedure
- Exceptional SPD process, traceability and willing to clean/sterilize expired instruments (this was preferred)
- Feasibility confirmed

dVP Savings Example: w/30% off List Price

Prostatectomy – da Vinci Si	Current List Pricing (new Instruments)			New List Pricing (with refurbished)		
Instruments/Accys:	Price per use	Price instrument	number of use	Price per use	Price Refurb instrument	number of use
Tip Cover Accessory	20.00€	20.00€	1	20.00€	20.00€	1
Hot Shears™ (Monopolar Curved Scissors)	320.00€	3,200.00€	10	224.00€	2,240.00€	10
Large Needle Driver	220.00€	2,200.00€	10	154.00€	1,540.00€	10
Maryland Bipolar Forceps	270.00€	2,700.00€	10	189.00€	1,890.00€	10
ProGrasp™ Forceps	220.00€	2,200.00€	10	154.00€	1,540.00€	10
4 arm Disposable Accys Kit, Disposable Obturator, Camera Trocar (3 rd party)	320.00€	320.00€	1	320.00€	320.00€	1
da Vinci price per procedure sum	1,370.00€			1,061.00€		
	274.00€	20% VAT		212.00€	20% VAT	
	1,644.00€	Total I&A		1,273.00€	Total I&A	

23%
cost savings

Economic Benefits to Hospital	Operational Benefits to Hospital
<ul style="list-style-type: none"> ➤ Reduced per procedure price ➤ Cost flexibility options to the surgeon and hospital ➤ Reduce cost of disposable at the hospital (500€ per 1000 kilogram of waste) 	<ul style="list-style-type: none"> ➤ Reduction in waste ➤ Recycling of valuable material ➤ Equivalent cleaning & sterilization process for refurb instruments

Additional Value
to the Hospital

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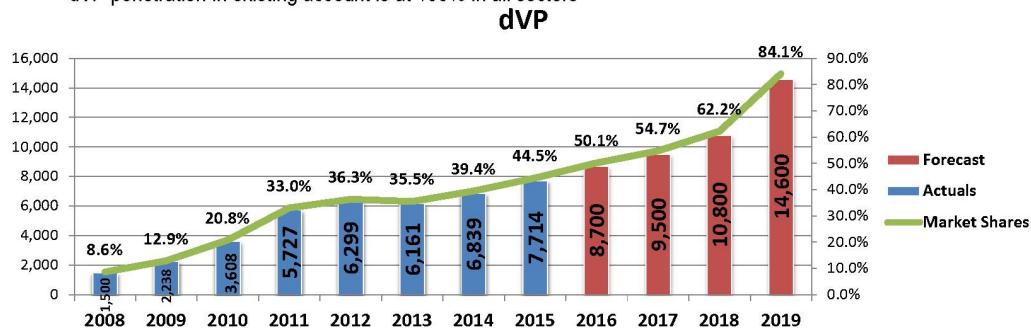
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EXAMPLE: Private Hosp. Economics – France

TOP PROCEDURE TARGETED FOR REFURBISHMENT PROGRAM	AVERAGE HOSPITAL REIMBURSEMENT PRIVATE vs. PUBLIC (for procedure in €)	CURRENT PRIVATE HOSPITAL COST for dVP (based on 150 procedures per system per year)	INTENDED PRIVATE HOSPITAL COST for dVP w/REFURBISHMENT PROGRAM (based on 200 procedures per system per year)
1) Prostatectomy	Private = 3,400€ Public = 5,907€	I&A = 1,644€ System/Service (Amortized) = 1,594€ Total System + Service + I&A = 3,238€	I&A = 1,273€ System + Service (Amortized) = 1,222€ Total System + Service + I&A = 2,495€

Notes: Private sector has significantly lower DRGs than Public hospitals since it doesn't cover operative exams + surgeons wages
Most of remaining dVP opportunity lies in Private for Profit sector (~7'000)
dVP penetration in existing account is at 100% in all sectors



Source: 2016 LRM French Market, Sept. 2016

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Pilot Program Design

Goal 1: Measure the effect on dV procedure volume of offering lower priced core instruments over three quarters at two existing customers.

Success Criteria: Outpace long-range procedure targets for France

Goal 2: Execution of expired instrument return policy for closed loop system

Success Criteria: Return of all expired instruments for three quarters

Pilot Site Selection Rationale:

- Private hospital in France
- Two years of dVP involvement
- Acceptance of QTI processes
- Adoption of expired return policy
- Excess capacity of 40% or less



- 2016 Procedures – 179
- One *da Vinci Si* Surgical System
- Feasibility confirmed



- 2016 Procedures – 187
- One *da Vinci Si* Surgical System
- Feasibility confirmed

What Franchise to Pilot?

da Vinci Si Instruments

- France & Germany asking for Si (1st phase)
- Private hospitals in France are the primary targets, mainly *Si* owners (more cost sensitive)
- Target procedure in GSA is Prostate, of which most dVPs are on dV *Si*
- Represents 67% of existing business (procedure growth is flat)
- *Si* Pre-owned + Lower Service Cost + Lower I&A Cost = GF opportunity in France
- Lower I&A Cost results in GF and incremental system opportunity in Germany
- Rebotix has potential to impact *Si* sales
- Lower capital costs for *Si* manufacturing lines

da Vinci Xi Instruments

- May incentivize customers to move to higher capability platform (X or Xi)
 - Advanced instrumentation, Multi-quadrant, etc.
- Enables use of advanced technology in emerging procedures in Germany
- Strengthen the benefit of *da Vinci X* platform for cost-sensitive customers
- Unique instrument Sequence Numbers may enable additional traceability for risk mitigation (recall exposure)

* Not currently being reprogrammed by 3rd parties

Recommendation, Timing & Cost

- **Recommendation:** Instrument eX (exchange) Project to proceed with pilot at select hospitals in French and German markets with **green housing instruments** to test assumption of market elasticity
- **Timing to start:** Minimum 3 months to begin (9 months duration)
 - Establish core team through PMO
 - Confirm plan with Notified Body
 - Signed contract with Hospitals
 - Set up reclaiming activity at Hospitals
 - Design Control/MCF for Green Housing Instruments
- **Cost:**
 - Reclaiming set up for 2 Hospitals = \$0 as the test site reclamation activity will be supported through the existing SRS infrastructure.
 - Capital = \$0
 - Design Control/MCF ~ \$100k - \$250k

Questions? & Discussion



Back Up Slides

Bob's Summary request

- Project plan/timing
- Expense/investment
- Selected sites/rationale
- Duration and success criteria

Proposed Strategy

Pilot: Select hospitals with excess dV capacity who express a need to lower dV costs to determine if a 30% reduction in instruments price results in incremental procedures.





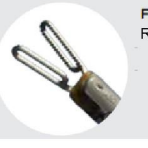
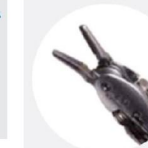
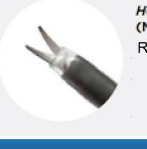
Create a process to reclaim expired multiport, multi-life 8mm Endowrist instruments and track results of the pilot to show benefits of participating.

Sell discounted new 'Green Cover' Instruments with "may contain refurbished parts" labeling to test theory of market elasticity. Returned instruments will be remanufactured by replacing specific components to return to original performance specifications to be sold at a lower ASP.

INTUITIVE SURGICAL REFURBISHMENT PROGRAM

Description:

Collection of expired *EndoWrist* Instruments at the hospital, return to Intuitive Surgical, and receive a refurbished instrument at a lower cost compared to new.

 <p>ProGrasp™ Forceps Refurbished</p>	 <p>Cadiere Forceps Refurbished</p>	 <p>Maryland Bipolar Forceps Refurbished</p>
 <p>Mega SutureCut™ Needle Driver Refurbished</p>	 <p>Fenestrated Bipolar Forceps Refurbished</p>	 <p>Large Needle Driver Refurbished</p>
 <p>Hot Shears™ (Monopolar Curved Scissors) Refurbished</p>		

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Instrument Refurbishment Program Benefits

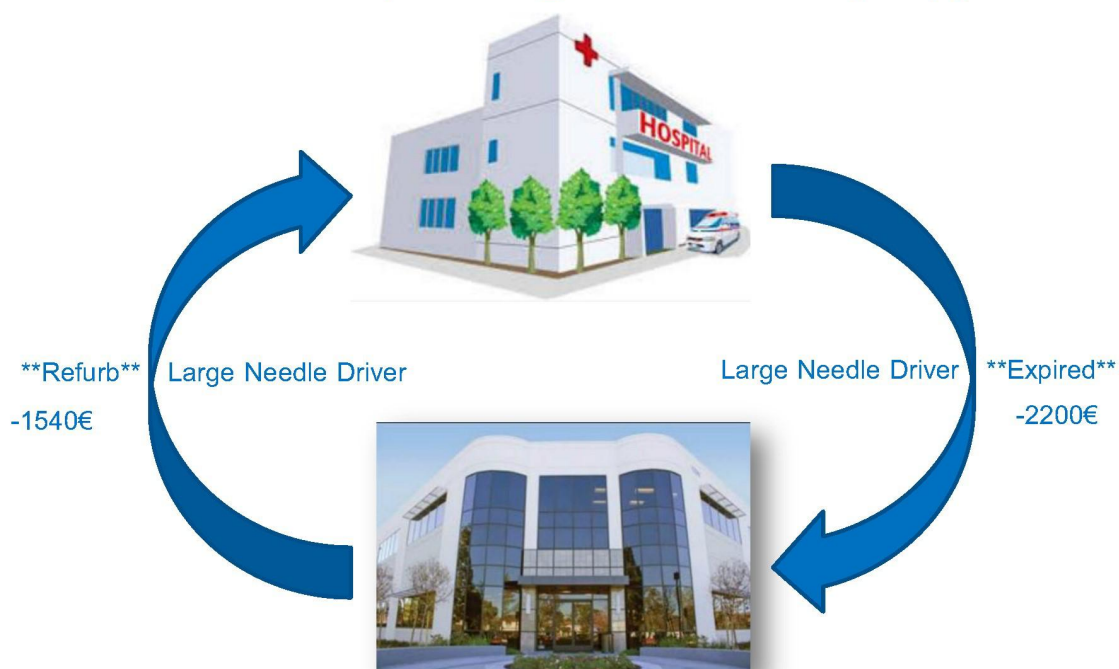
Description:

Reclaim expired instruments for the purpose remanufacturing and recertifying to original performance specifications.



Clinical Performance	Economic Benefits	Operational Benefits
<ul style="list-style-type: none"> ➤ Equivalent performance ➤ 10 lives per instrument ➤ Equivalent cleaning & sterilization process 	<ul style="list-style-type: none"> ➤ Reduced per procedure cost ➤ Cost flexibility options to the surgeon and hospital ➤ Reduce cost of disposable at the hospital (500€ per 1000 kilogram of waste) 	<ul style="list-style-type: none"> ➤ Reduction in waste ➤ Recycling of valuable material

Closed Loop Program 1:1 by Type



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Two Large IDN's in France were Visited

Goal: Determine economic feasibility of lower cost-per-procedure solutions to increase dV penetration with key IDN partners



The public hospital system (établissement public de santé) of the city of Paris and its suburbs

- Recognized their da Vinci program can be used more effectively, and lower I&A per procedure cost would help in consuming excess capacity
- Feasibility confirmed

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The first cooperative group of independent clinics, in the form of a subsidiary of its parent companies.

- Higher cost of dV I&A limits the use of da Vinci and refurbished instruments would be accepted by surgeons
- Recognizes the removal of all dV instruments from the hospital is a great value alone
- Feasibility confirmed

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Market Analysis – France

				Comments
How much of a barrier is Instr. cost to dV adoption?	None	Minimal	Significant	Customers are losing 300K-600K per year on a dV program due to low reimbursement
Market acceptance of Refurbished Instrs?	No	Some	Acceptable	See market research done by Todd's visit
What Instr offerings are most desired?	Si (first phase)		Xi (second phase)	Anything related to Urology, especially in Prostatectomy
Are there 3 rd party low cost activities in your region?	No		Yes	Rebotix
What procedures will be targeted with Refurbished Instruments?	Sell a system then capture 100% of robot prostate (dVP). Maybe growth in pyloplasty and sacro colpopexy with lower cost of instrumentation			
Describe market tactics to drive incremental volume (Accounts, Procedures, management of current business, ...)	<p>Driving adoption of "X" system in private hospitals. At 1.3 M Euro will be challenging. A combination of lower service, lower Si pre-owned and lower I&A prices for Si will drive procedure volume in Urology</p> <p>Si pre-owned is 550 – 600K per hospital. ASK is 350K - 450K € in IDN for France to drive adoption in Urology</p> <p>Greenfield private hospitals likely not accepting 1.3 M Euro. Xi/X refurb may not be accepted by the French team due to the type of hospital (University) is already an Xi adopter.</p>			

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Open questions:

France may not be able to limit the program to only certain customers (Romain or Cyprian). Question – contract with customers for the refurbishment requirements, if they don't comply then they would not be eligible for the refurbished instruments.

If they do not contract with intuitive, and they order the refurbished instruments, are we obligated to fulfill that order.

Do we have any "say" in where the refurbishment instruments are being used in only certain procedures?

Market Analysis – Germany

How much of a barrier is Instr. cost to dV adoption?	None	Minimal	Significant	In average customers claiming I&A price difference of ca 1200 € open vs robotic.
Market acceptance of Refurbished Instrs?	No	Some	Acceptable	As long as the specs are identical, it comes from the same manufacturer and the price is sign. Lower – high acceptance
What Instr offerings are most desired?	Si (first phase)	Xi (second phase)		Anything related to Urology, especially in Prostatectomy
Are there 3 rd party low cost activities in your region?	No	Yes		Rebotix
What procedures will be targeted with Refurbished Instruments?	Target indications By getting a 30% off, we could start to target dVHb. The benefit of this will be to create incremental indications vs discount to the customer With the reimbursement in dVHc, and dVLAR, we can already be profitable if we count the DRG			
Describe market tactics to drive incremental volume (Accounts, Procedures, management of current business, ...)	The I&A is one important piece of the decision-making process when acquiring a dV, by having option to lower I&A cost with 30% we expect that we can sell some additional GF and Incremental Note the risk that we need to define a strategy to manage - if we offer one customer, others will demand the same. These other customer might not have same incremental procedure growth potential so loss of revenue if we offer same.			

Target accounts

CAP accounts: Uni Tuebingen, Caritas (cap account for the GEN team)

RDI (Rechts der Isar)

Martini and Bochum Augusta to drive incremental system sales

Technical Assessment

- *Strategy: Two pronged*
 - *Select representative instruments that previously underwent formally life tested*
 - *Refurbish based on visual inspection and IPT to identify defective component*
 - *Select RMA instruments*
 - *Refurbish by replacing standard set of components*

Technical Assessment

- *In house instruments: N=4 each*
 - LND: 10 lives [Completed]
 - Prograsp: 10 lives [Completed]
 - FBF: 10 lives [Completed]
 - MCS: 10 lives [Pending]
 - Failure modes were not consistent; need to repeat testing with replacement of inputs, cables, and grips.
- *RMA instruments : N=4 LND*
 - Clinical performance was rated equivalent to new instruments (N=2)
 - Replace cables, inputs, and flush tube = survives 10+ lives

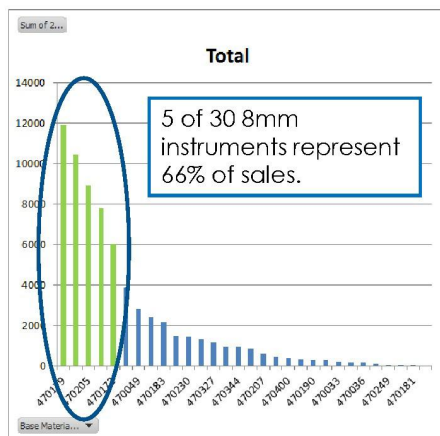
Technical Assessment

- *In house instruments*
 - Refurbishment Cost \$47-63
 - Refurbishment Duration ~49 min
- *RMA instruments*
 - Refurbishment Cost \$50 - \$100
 - Refurbishment Duration ~XX min

Note this is below the conservative estimate in financial model

Manufacturing Assessment

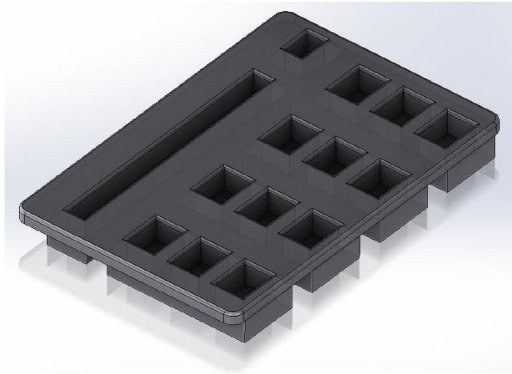
- **Pilot Phase:** 8mm Instruments (Top-5) by revenue
- **Roadmap:** Additional instruments / platforms (Xi/Si)



PN	Description	2016 Qty (TYD)	%	Cumulative
470179	8MM MONOPOLAR CURVED SCISSORS,IS4000	11893	18%	18%
470006	8MM LARGE NEEDLE DRIVER,IS4000	10470	15%	33%
470205	8MM FENESTRATED BIPOLAR FORCEPS,IS4000	8917	13%	46%
470063	8MM PROGRASP FORCEPS,IS4000	7792	11%	58%
470172	8MM MARYLAND BIPOLAR FORCEPS,IS4000	6011	9%	68%
470306	8MM MEGA SUTURECUT ND,IS4000	3867	6%	72%
470049	8MM CADIERE FORCEPS,IS4000	2909	4%	76%
470347	8MM TIP-UP FENESTRATED GRASPER,IS4000	2412	4%	80%
470183	8MM PERMANENT CAUTERY HOOK,IS4000	2176	3%	83%
470184	8MM MEGA NEEDLE DRIVER,IS4000	1482	2%	85%
470230	8MM LARGE HEM-O-LOK CLIP APPLIER,IS4000	1446	2%	87%
470318	8MM SMALL GRASPING RETRACTOR,IS4000	1320	2%	89%
470327	8MM MEDIUM-LARGE CLIP APPLIER,IS4000	1174	2%	91%
470184	8MM PERMANENT CAUTERY SPATULA,IS4000	991	1%	92%
470344	8MM CURVED BIPOLAR DISSECTOR,IS4000	959	1%	94%
470296	8MM LARGE SUTURECUT NEEDLE DRIVER,IS4000	839	1%	95%
470207	8MM TENACULUM FORCEPS,IS4000	613	1%	96%
470401	8MM HORIZON SMALL CLIP APPLIER,IS4000	458	1%	97%
470400	8MM LONG BIPOLAR GRASPER,IS4000	394	1%	97%
470001	8MM POTTS SCISSORS,IS4000	339	0%	98%
470190	8MM COBRA GRASPER,IS4000	312	0%	98%
470048	8MM LONG TIP FORCEPS,IS4000	297	0%	99%
470033	8MM BLACK DIAMOND MICRO FORCEPS,IS4000	224	0%	99%
470007	8MM ROUND TIP SCISSORS,IS4000	187	0%	99%
470036	8MM DEBAKEY FORCEPS,IS4000	172	0%	99%
470171	8MM MICRO BIPOLAR FORCEPS,IS4000	103	0%	100%
470249	8MM DUAL BLADE RETRACTOR,IS4000	94	0%	100%
470246	8MM ATRIAL RETRACTOR SHORT RIGHT,IS4000	69	0%	100%
470181	8MM RESANO FORCEPS,IS4000	63	0%	100%
470215	8MM CARDIAC PROBE GRASPER,IS4000	43	0%	100%
Grand Total		67888	100%	100%

Manufacturing Assessment

- WIP trays



Manufacturing Assessment

Part Number	Material Name	Retain	Scrap	TBD	Grand Total
470006-10	8MM,LARGE NEEDLE DRIVER,IS4000	\$ 99.55	\$ 56.59	\$ 13.19	\$ 169.33
470049-04	8MM,CADIERE FORCEPS,IS4000	\$ 109.68	\$ 63.63	\$ 3.45	\$ 176.76
470093-09	8MM,PROGRASP FORCEPS,IS4000	\$ 92.19	\$ 66.47	\$ 3.45	\$ 162.11
470172-13	8MM,MARYLAND BIPOLAR FORCEPS,IS4000	\$ 115.13	\$ 66.84	\$ 25.28	\$ 207.25
470179-14	8MM,MONOPOLAR CURVED SCISSORS,IS4000	\$ 47.06	\$ 185.75	\$ 24.33	\$ 257.14
Grand Total		\$ 463.61	\$ 439.28	\$ 69.70	\$ 972.59

Part Number	Material Name	Retain	Scrap	TBD	Grand Total
470006-10	8MM,LARGE NEEDLE DRIVER,IS4000	59%	33%	8%	100%
470049-04	8MM,CADIERE FORCEPS,IS4000	62%	36%	2%	100%
470093-09	8MM,PROGRASP FORCEPS,IS4000	57%	41%	2%	100%
470172-13	8MM,MARYLAND BIPOLAR FORCEPS,IS4000	56%	32%	12%	100%
470179-14	8MM,MONOPOLAR CURVED SCISSORS,IS4000	18%	72%	9%	100%
Grand Total		48%	45%	7%	100%



Regulatory Assessment

- Country by country assessment on ability to sell refurbished instruments, and requirements to do so.

Questions:

- Allows sale of refurbished product made anywhere?
- Only allow sale of refurbished product if refurbishing done in country?
- Clearance/registration required?

Regulatory Assessment

Country	Allows sale of refurbished product made anywhere?	Only allow sale of refurbished product if refurbishing done in country?	Clearance/ registration required?	Time to complete registration
US	Yes	No	No	NFJ; no timeline.
Canada	Yes	No	Yes	Amendment- 6 months.
France	Yes	No	Yes	Must be CE Marked; notification after placing on the market.
Germany	Yes	No	Yes	Must be CE Marked.
India	Yes	No	No	Can change depending on 1. New regulation for medical devices and 2. restriction on importation of used devices (attempted in summer 2015).
China	No	No		Hospitals are allowed to purchase and use used devices from other hospitals within China. However, companies are not allowed to sell refurbished products.
Japan	Yes	No	Yes	Registration required only if facility has not been registered. 1 year or so.
Korea	Yes	No	Yes	6-12 months Only products with the same information that have been authorized in the Sanitary register (PN and Country). It does not matter if it is remanufactured.
Mexico	Yes	No	Yes	N/A
Singapore	Yes	No	No	N/A
Malaysia	Yes	No	No	N/A

Regulatory Assessment

Country	Allows sale of refurbished product made anywhere?	Only allow sale of refurbished product if refurbishing done in country?	Clearance/ registration required?	Time to complete registration
Indonesia	No	No	No	N/A
Vietnam	No	No	No	N/A
Philippines	Yes	No	No	N/A
Thailand	No	No	No	N/A
Taiwan	Yes	No	Yes	13-18 months, including QSD.
Australia/NZ	Yes	No	No	N/A
Argentina	No *	No	No	<ul style="list-style-type: none"> The device must be reconditioned in the country of origin. Must be made by the original manufacturer. It has to be imported by direct user of the used good and the import operations will be subject to the verification regime of destination for the term of 4 years. In order to carry out the importation, the approval of the Ministry of Commerce of the Nation is required.
Chile	Yes	No	No	N/A
Colombia	Yes	No	Yes	30 days

*Argentina allows refurbishment when performed in country of origin

Regulatory Strategy – Green Housing

- Discuss with Carsten – has his CE mark
 - Testing whether surgeons will use refurbished instruments
 - *Xi* instruments only
 - Instrument is actually new, but customer believes it may have some used parts
 - Has green housing (same color as used with *Si* SS) for differentiation
 - Propose “No formal notification and no change to product listing”



Legal Opinion from EU Counsel

Redacted for Privilege